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Clinical Research and the Delivery of Excellence

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To many, the natural path to clinical excellence would lie through a “professional” rather than a ‘commercial’ approach, with ‘management’ seen as a function of the latter, not the former. This article argues that critical care managers can deliver clinical excellence through a modern commercial approach, that engagement in clinical research facilitates this approach, and explores the barriers, and solutions, to clinical research.

The word 'brand' was derived from the old Even in the face of convincing evidence clinTo many, the natural path to clinical excellence would lie through a ‘professional’ rather English word brond, meaning a fire, flame or piece of burning wood, and in the 1550s described the process of marking livestock with a hot iron in order to identify to whom the belonged. By the early 19th century the proprietorial connotation of the word had expanded to refer to goods 'belonging' to a specific manufacturer or supplier. In the contemporary commercial sense the word now describes a much larger concept. 'Brand' now conveys the emotional and psychological link between a business (or institution, or hospital) and its “customers” and conveys complex messages relating to value and quality; intangible but highly valuable properties. Far from irrelevant 'marketing spin' the importance and value of the concept is reflected in the exponential increase in academic papers published in peerreviewed business journals with the word Even in the face of convincing evidence clinTo many, the natural path to clinical excellence would lie through a ‘professional’ rather 'brand' in the title (Figure 1). But the concept of 'brand' not only has value externally, to the market, but also internally to the business itself as a means of remaining faithful to the core values (innovation, durability, design excellence, practicality, value etc…) that yielded the external brand dividend in the first place. The external value of branding is reflected in tangible benefits such as brand loyalty, market share (competitive advantage), brand equity and share Even in the face of convincing evidence clinTo many, the natural path to clinical excellence would lie through a ‘professional’ rather and happy…”. Will Durrant’s oft-quoted interpretation of this sentiment that " excellence … is not an act, but a habit" is the price. For those who think this only applies in commerce one only has to think of organisations with internationally recognised 'brands', for example Harvard University, Oxford University, or Cambridge University, to see that this is not the case (Sung and Yang 2008); and this is no less true for healthcare organisations (Knapp 2001).

To build a brand you have to know what a brand is...and what a brand is not. A brand is not your logo, product, personal identity, plush corporate offices, employees, corporate culture, or even what you say it is Even in the face of convincing evidence clinTo many, the natural path to clinical excellence would lie through a ‘professional’ rather and happy…”. Will Durrant’s oft-quoted interpretation of this sentiment that " excellence … is not an act, but a habit" is the (2009). Your brand is generated and sustained in the minds and hearts of people who interact with your organisation – be they patients, the professionals who refer patients, relatives, professional visitors (including students and trainees), inspectors, local and central government politicians, the media, or suppliers of other goods and services. It reflects the way you are, not the way you aspire to be. This is a long-recognised truth. Twenty-four centuries ago Aristotle wrote in the Nicomachean Ethics “…the good of man is a working of the soul in the way of excellence in a complete life…for as it is not one swallow or one fine day that makes the spring, so it is not one day or a short time that makes a man blessed and happy.....”Will Durrant’s oft-quoted interpretation of this sentiment that” excellence ....is not an act, but a habit”is the Even in the face of convincing evidence clinTo many, the natural path to clinical excellence would lie through a ‘professional’ rather and happy…”. Will Durrant’s oft-quoted interpretation of this sentiment that " excellence … is not an act, but a habit" is the thread that runs through Peters and Waterman’s seminal 1982 management book "In Search of Excellence" (Peters and Waterman 2004) in the sense of a corporate "habit" shared throughout the work force. A clinical culture that embraces clinical research has woven within its fabric the strands that lead to clinical excellence. Is this really so? In the UK's National Health Even in the face of convincing evidence clinTo many, the natural path to clinical excellence would lie through a ‘professional’ rather and happy…”. Will Durrant’s oft-quoted interpretation of this sentiment that " excellence … is not an act, but a habit" is the Service, for example, there is a significant difference in the number of publications listed in the US National Library of Medicine's PubMed database for the last five years between the ten best and ten worst performing hospitals (Figure 2). So how might the link between clinical research activity and excellence arise?

Clinical Research and Clinical Practice

History has repeatedly shown us that, unencumbered by external oversight of either clinical efficacy or financial probity, clinicians offer therapy based on “a moral commitment to intervention…even in the absence of reliable knowledge” (Freidson 1988) resulting in a geographical variation in clinical practice inexplicable by the demographics of disease (Millenson 1997). Even in the face of convincing evidence clin ical practice has been slow to change, with a significant financial and human cost attached to the laggard’s professional autonomy. The current challenge is therefore “to promote the uptake of innovations that have been shown to be effective, to delay the spread of those that that have not yet been shown to be effective and to prevent the uptake of ineffective innovations” (Haines and Jones 1994), with the aim of maximising efficacy and minimising costs. The factors that determine the evidence-based migration of practice are acknowledged to be complex, poorly defined and inter-twined, and relate to the innovation, the adopters, the process of diffusion, the organisation, and the extra-organisational environment (Greenhalgh et al. 2005). An environment in which management-supported multi-disciplinary research is the norm will have attributes that have been shown to facilitate the adoption of innovative practice. These include familiarity with the process of sourcing, collating and appraising research evidence; an instinct to question tradition or convention; an enhanced capacity to absorb new knowledge; and enlarged horizons in which the possibilities of alternative strategies can be seen (Greenhalgh et al. 2005). Moreover an organisation that is comfortable with the evaluation of experimental therapies is less likely to view change with suspicion. Participation in the development and evaluation of new strategies also enhances uptake (Greenhalgh et al. 2005), as was shown in the evaluation of the National Cancer Institute’s ‘Community Clinical Oncology Program’ for the management of breast cancer. When this was evaluated in 1995 the investigators commented “[oncologists who participated in ongoing clinical trials] were more likely to adopt the new treatment, adopted it at a much faster rate, and were less likely to abandon the state-of-the-art treatment after initial use (Warnecke et al. 1995).” Useful by-products of research arise from the process by which the results of this activity are disseminated and include the generation of an institutional reputation for innovation and the production of national ‘opinion leaders.’ Positive influence from the latter has also been shown to help with the adoption of change (Greenhalgh et al. 2005) and, if nationally recognised, can result in the organisation acting as a ‘pace setter’, rather than having to adopt innovations developed by others.

Clinical research activity can also have benefits at the bedside for both patients and staff. There is evidence of better outcomes for patients who participate in clinical studies compared to those who do not (Braunholtz et al. 2001; Robinson et al. 2009; Hallstrom et al. 2003), whilst the presence of additional research staff provides additional flexibility of rostering, and the availability of research-related assays or equipment enhances the interest and educational value of the clinical environment. An enhanced profile from a presence on the national research stage improves both the quantity and quality of job applicants, easing recruitment. Similarly, a vibrant and inquisitive clinical atmosphere associated with innovations recognised nationally contribute to job satisfaction, organisational pride and an ‘esprit de corps’ - qualities more related to employee satisfaction than either wages or benefits (Charmel 2009), with knockon benefits in terms of enhanced productivity, reduced absenteeism, and reduced staff turnover. So if clinical research activity is a route to clinical excellence what are the barriers to clinical research and how might these be overcome?

Barriers, and Solutions to Clinical Research

National Strategy Level

In the UK the importance of clinical research in improving both the quality and cost-effectiveness of healthcare have only been recently recognised. In 2006 the government published ‘Best Research for Best Health’ (2006), an important and far-reaching review of the UK’s national clinical research strategy. Two key strands of this review were, on the one hand, the restructuring of national R&D funding and, on the other, simplification of the research governance process.

Historically R&D funding included the ‘Service Increment for Teaching and Research’, the ‘Locally Organised Research Scheme’ research budgets managed by the and delivered to investigators via cashstrapped hospital management, on the other. For some critical care units this arrangement has allowed the recruitment of research nurses, enabling them to participate Department of Health and the Regional Health Authorities, as well as specific allocations to the London Postgraduate Special Health Authorities. Following the Cullyer Report in 1994 these allocations were brought together in 1998 as the ‘NHS R&D Levy’, but the fairness and appropriateness of these allocations was open to question and the potential for recipient organisations to divert these funds to front-line activities made this an ineffective way of supporting research. Starting in April 2006, therefore, the ‘NHS R&D Levy’ was gradually withdrawn in a three year transitional arrangement and, over the same period, an increasing source of funding became available through the UK’s newly formed National Institute for Health Research (NIHR) supporting NIHR Infrastructure, NIHR Faculty, and delivered to investigators via cashstrapped hospital management, on the other. For some critical care units this arrangement has allowed the recruitment of research nurses, enabling them to participate NIHR Programmes and NIHR Systems. Much of this funding is now disbursed as targeted and auditable grants; a mechanism resistant to diversion by recipient healthcare organisations. However, funding to meet the NHS Service Support Costs of NIHR studies is now channelled through 25 ‘Comprehensive Local Research Networks’ and 6 ‘Topic Specific Networks’ but still paid to healthcare organisations, rather than investigators. These allocations are now within the gift of regional, variably efficient, potentially partisan, quasi-autonomous organisations on the one hand,and delivered to investigators via cash strapped hospital management ,on the other. For some critical care units this arrangement has allowed the recruitment of research nurses, enabling them to participate and delivered to investigators via cashstrapped hospital management, on the other. For some critical care units this arrangement has allowed the recruitment of research nurses, enabling them to participate in national and local studies. For others, however, funds meant to support research have failed to reach the investigators. Evidence that this is the case comes from a recent UK-wide survey conducted prior to the 2009 meeting of the UK Critical Trial Forum which showed that although 78% of the respondent’s hospitals had recruited critical care patients into a study, only 45% employed a research nurse (Mackenzie et al. 2010). When negotiations between the hospital and CLRN are unsatisfactory, there may be recourse for action by appealing to the Network Board or, failing that, through the CLRN complaints and governance route. On the other hand, persuading a hospital not to help itself to an overly generous proportion of the funding cake is a different and delivered to investigators via cashstrapped hospital management, on the other. For some critical care units this arrangement has allowed the recruitment of research nurses, enabling them to participate matter, particularly if the hospital is one of the new breed of autonomous Foundation Trusts, answerable only to Monitor. Under these circumstances there may be little researchers can do to change attitudes and without a proven track record in clinical research or ‘big names’ to secure high value and prestigious, clinical research grants, the situation is a ‘Catch 22’.

The Integrated Research Application System (IRAS) was introduced in 2008 as a webbased platform designed to prevent duplication of data collection for clinical research regulatory approvals in the UK. Although this has simplified the process the regulatory burden in the UK remains substantial, to the point that the proportion of the world’s clinical trials conducted in the UK fell 66% from 2000 to 2006, and the number of National Research Ethics applications fell 35% from 2004/5 to 2009/10. In January 2010 the UK Academy of Medical Sciences (AMS) expressed

concern about the negative impact of the regulatory burden, a view echoed more recently by the BMA's annual Conference of Medical Academic Representatives, and on the 25th March 2010 the AMS was asked by the then Secretary of State for Health, Andy Burnham, to review regulation and governance in this area. Nevertheless regulatory burden will remain until this review is completed and its conclusions acted upon.

Organisational Level

In the UK Government-set targets have become the measure by which hospitals are judged, forcing resources to be focused on meeting these targets. Without specific incentives, therefore, or a visionary understanding of the medium- and long-term benefits of clinical research, hospital managers are unwilling to provide effective support in a number of ways (Table 1). Reporting by hospitals of the number of research participants, described in the NHS Operating Framework for 2010/11, may help a little but without stronger incentives little is likely to change in the immediate future.

Clinicians

Between 2001 and 2006 there has been a 12.5% reduction in the total number of clinical academics, defined as those with a substantial proportion of their job allocated to research. Within anaesthesia, the parent discipline of most of the UK's intensivists, clinical academic posts have fallen by 11% in the period 2000 to 2005 and two departments have closed entirely (Pandit 2005). In general, the decline in academic medicine has been attributed to disincentives to entry and barriers to progression (Bell 2003). In addition academic anaesthesia has fallen out of favour within universities because of its marked inability to attract significant research funding3 or to score highly in the Research Assessment Exercise (RAE), a system that determines a university's income from Higher Education Funding Councils (HEFC) for research activities and infrastructure. It remains to be seen whether changes to the training structure for clinical academics, described in the Walport Report (Academic Careers SubCommittee of MMC and the UKCRC, 2005), will have the desired effect with regards to recruitment and retention, or whether academic anaesthesia can be resuscitated by the Royal College of Anaesthetists' 2005 strategy (Pandit 2005).

Non-academic consultant medical staff in the UK may have 21-25% of their working week allocated to 'research, teaching, audit and continuing professional development', but little could realistically be achieved with the pro-rata research allocation of 2.5 hours per week. Insufficient time for research was identified by a number of respondents in the UK Critical Care Trials Forum (UKCCTF) 2009 survey as a reason for not participating in research (Mackenzie et al. 2010). Given that research would thus entail the commitment of non-NHS time, competing with time more lucratively spent in the private health sector, it is not surprising that only 10-15% of NHS anaesthetic consultants (Pandit 2005) express any interest in research. As clinical research has always played a very minor role in anaesthetic training in the UK few critical care clinicians have any expertise in research methodology, such as formulating an appropriate research question, study design, securing funding, or analysing data. These were all identified in the UKCCTF survey as areas where support and education would be appreciated (Mackenzie et al. 2010). Where regional or national collaboration might have provided access to these missing skills, it appears that this is currently impeded by regional rivalries and distrust. Nevertheless, the future of large-scale clinical trials will only be possible through regional collaborations amongst like-minded clinicians as in, for example, the West Midlands, or by national collaborations supported by the UK's Intensive Care Society or brought together through the UK's Clinical Trials Forum.

Conclusion

In modern healthcare the pursuit of excellence is as much a commercial, as a professional, imperative and is best achieved in a culture that embraces clinical research. National and organisational strategies must nurture and facilitate multi-disciplinary participation in clinical research.

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